MEMORANDUM OF MEETING

between the Food and Drug Administration
and the Healthcare Distributors Management Association

October 16, 2002
Parklawn Building
Rockville, Maryland

Attendees:

HDMA
Jon Borschow, Board Chairman-Elect
Ron Strech, President
Lisa Clowers, Vice-President of Standards and Technology
Michael Gallo, Associate Director, Distribution Logistics
John Howells, Associate Director, E-Business

Auto-ID Center, Massachusetts Institute of Technology
David Brock, Founder and Director
Robin Koh, Associate Director

FDA
William K. Hubbard, Senior Associate Commissioner for Policy, Planning, and Legislation
Teresa Mullin, Associate Commissioner for Planning
Thomas McGinnis, Office of Policy, Planning, and Legislation
Philip L. Chao, Office of Policy, Planning, and Legislation
Randy Levin, Center for Drug Evaluation and Research
Mary Gross, Center for Drug Evaluation and Research
Howard Muller, Center for Drug Evaluation and Research
Jay Crowley, Center for Biologics Evaluation and Research

This was a follow-up meeting to the September, 17, 2002, meeting between FDA, HDMA, and others.

The HDMA representatives focused on the use of non-bar code technologies, particularly radio frequency identification (RFID). They indicated that RFID technology could be used for medication error prevention, patient labeling, identification of counterfeit drugs, and even terrorism situations.

Representatives from the Auto-ID Center gave a presentation describing their organization's work. In brief, the center is trying to develop standards for automatic identification and tracking and is also creating international centers. Sponsors include pharmaceutical firms, the EAN, vendors, and trade bodies. The system would revolve around electronic product codes (EPC)

which would be unique to each individual item. The RFID tags can be as small as 35 microns across, and the target cost is 5 cents per tag. The preference is to embed the tag in the product so that it cannot be removed. The tags can carry sensor information, too, such as temperature, weight, and moisture. RFID systems can read 100-400 tags per second.

The Auto ID Center representatives explained that the EPC is an extention of the Global Trade Item Number (GTIN) and supported by the UCC/EAN. They explained the components in the EPC and indicated that pilot programs are underway at the pallet and case level. The EPC would make it more difficult to counterfeit products.

The HDMA representatives suggested that FDA draft a rule to indicate what is desired rather than specify the use of any particular technology. FDA representatives asked whether the industry could agree on a particular technology itself, and the HDMA representatives believed that the affected industries could. As for RFID, they indicated that there is a need to develop an infrastructure, chips, antennae, and readers, but that the technology is still developing.